DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2169n

CERTIFIED MAIL
RETURN REGEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

# WARNING LETTER

October 9, 1998

WL-4-9

**Inspection ID: 1973920004**

Dr. Thelma L. Chisholm
Medical Director
Thelma L. Chisholm, M.D.
5260 South Figueroa - Suite 106
Los Angeles, California 90037

Dear Dr. Chisholm:

We are writing you because on September 22, 1998, your facility was inspected by a representative of the Los Angeles County Health Department, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection and investigation revealed the following Level 1 findings at your facility:

1. No processor QC records were present: [redacted]
   Room ID = Darkroom.

The specific deficiency noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represent a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection and investigation. These Level 2 findings are:

2. Records for repeat analysis were not present..

3. No phantom image QC charts were present: [redacted] CORP. [redacted] Mammo.

4. No medical audit system to track positive mammograms was in place.

In addition, at the close of the inspection there were several instances of "Documents Pending". This was printed out and given to you as part of the inspection report:

1. Interpreting Physician's Continuing Experience: [redacted]

2. Interpreting Physician's Continuing Experience: [redacted].

3. Interpreting Physician's Continuing Experience: [redacted]

4. The Interpreting physician's documentation of having read or interpreted mammograms from the examination of at least 240 patients in 6 months: [redacted]

5. Interpreting physician's board certificate: [redacted]

6. Interpreting physician's 40 CME hours: [redacted]

7. Interpreting physician's license to practice medicine: [redacted]

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to **correct** all of the violations noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records **(Note: Patient names or identification should be deleted from any copies submitted)**

Please submit your response to:

Robert W. Nicol
Compliance Officer
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please fell free to contact Robert W. Nicol at (949) 798-7667.

Sincerely yours,

for Elaine C. Messa
District Director

cc: Mr. Bob Ortego, MQSA Inspector
County of Los Angeles
Department of Health Services
Radiation Management
550 South Vermont Avenue, Room 600
Los Angeles, CA 90020